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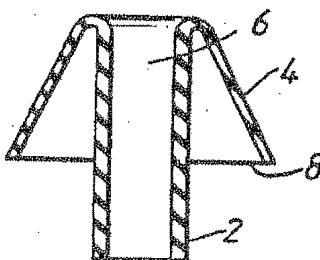
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With amended claims and statement.

(54) Title: NASAL CANNULA



(57) Abstract

A nasal cannula comprising a generally tubular insert element which has a distal portion (4) to be placed in a nasal cavity and a proximal portion (2) for connection to a supply line (10) for oxygen or oxygen-enriched gas is characterised in by the distal portion (4) being formed of a flexible and resilient material and having a divergent, generally frusto-conical, configuration. The cannula provides a positive and comfortable fit in the nasal cavity, making it efficient in administering supplied gas and facilitating control over inspired oxygen concentration. It is conveniently used with the high-humidity, high-flowrate oxygen-enriched air supplied by oxygen concentrators employing gas-separation membranes.

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NASAL CANNULA

This invention relates to a nasal cannula, in particular to a nasal cannula for the supply of breathing gases.

Nasal cannulas are frequently used in administering oxygen or oxygen-enriched air, especially to patients suffering from impaired lung conditions.

The portion of a conventional cannula to be placed in the patient's nasal cavity is generally a simple tubular insert made of medically compatible plastics material. It is arranged to fit loosely in the nasal cavity, providing a channel for the administration of the desired gas or gas mixture, and is connected to a flexible supply tube for the administered gas. Such simple tubes tend however to be fairly rigid and uncomfortable for the patient to wear, particularly if the administered gas is dry, and can even lead to pressure necrosis if they persistently rub on the walls of the nasal cavity.

The cannula of the present invention is described herein mainly with reference to the administration of oxygen or oxygen-enriched gases but is also applicable to the supply of breathing gases in general, including supply of air (for example in a smoke-filled environment) and of anaesthetic or analgesic gaseous mixtures.

In the administration of oxygen or oxygen-enriched gases the loose fitting of the cannula has been required in order to avoid prolonged inhalation of high concentrations of oxygen. Long-term inhalation of high oxygen concentrations can cause serious medical side-effects, especially for a chronically ill patient. The flow-rate of oxygen fed through the cannula to such patients is accordingly limited to about 2 to 3 litres per minute and the loose fitting permits dilution with ambient air inspired together with the oxygen.

Several drawbacks arise from this method of treatment because of variations in the types of cannula and in its inherent lack of control over the relative proportions of administered oxygen and the diluting air. The conventional cannulas are often worn wrongly, can easily become dislodged and can lead to unacceptable oxygen supply levels.

Ideally the oxygen administration requires delivery to the lungs of air containing a predetermined degree of oxygen enrichment under controlled conditions. Patients suffering from irreversible forms of lung impairment, however, require long-term oxygen treatment and are commonly provided with oxygen supply and cannula equipment for use at home. Under home conditions medical supervision is generally limited, equipment for monitoring saturation levels is not usually present and control is often effected by the patient alone. These factors increase the risks of either insufficient or excessive blood-oxygen content. In addition to the medical risks the selection of excessive oxygen can also be a general safety risk in allowing undue build-up of the oxygen concentration in the ambient air, with resultant combustion hazards.

The present invention consists of a new design of nasal cannula which overcomes the above-mentioned problems.

According to the invention there is provided a nasal cannula comprising a generally tubular insert element which has a distal portion (4) to be placed in a nasal cavity and a proximal portion (2) for connection to a supply line (10) for oxygen or oxygen-enriched gas, characterised in that the distal portion (4) is formed of a flexible and resilient material and has a divergent, generally frusto-conical, configuration.

Compared with previous proposals the cannulas according to the invention present a more positive fitting in the nasal cavity, making them more efficient in administering the supplied gas. They permit improved control over the patient's inspired oxygen concentration even when the oxygen as such is supplied at low flowrates of pure or highly-enriched oxygen, for example from cylinders or from pressure swing concentrators. They are also particularly effective when used with the proportionately higher flowrates of moderately enriched oxygen levels with full humidification which can be supplied by oxygen concentrators employing gas-separation membranes. Indeed it is the availability of such concentrators, with their ability to deliver a consistent mixture with the optimum oxygen and moisture levels, which has increased the need for a more efficient cannula system.

The cannulas according to the invention have the further advantages of being more comfortable for the patient and less prone to accidental displacement and are therefore more likely to be properly used.

The divergent portion of the cannula is of such dimensions that its open end contacts the internal surfaces of the nasal cavity. It can be regarded as a flared skirt of which the end having the least diameter (the "waist") is attached to the distal portion and the end having the widest diameter (the "hem") contacts the interior of the nasal cavity. Because of the flexible nature of the constructional material the hem is able to conform to the specific internal shape of the cavity and thus to form a continuous seal therewith. Thus, when not in position in a nasal cavity the divergent portion will be of generally frusto-conical shape but when inserted into the cavity it adopts an irregular shape matching the internal contours of the cavity.

Typical dimensions for the cannula insert portions are as follows: external diameter of the proximal portion 5.0 to 7.0 mm; wall thickness of the proximal portion 0.5 to 0.8 mm; wall thickness of the skirt 0.3 to 0.5 mm; external diameter of the skirt hem 13.0 to 17.0 mm; and skirt length 12.0 to 16.0 mm. Such dimensions permit a single size of cannula suitable for most adult patients.

In the preferred version of cannula according to the invention the divergent portion is folded back such that the flared skirt extends around the proximal portion. This configuration offers several advantages. It facilitates insertion of the cannula into the nasal cavity, since the skirt waist is the first part to be inserted and can be comfortably inserted up to the point where the hem makes a firm contact with the interior of the cavity. It further permits the flexible skirt to act both as a one way-valve for the release of exhaled gas and as a good seal while the administered gas is inhaled.

For simplicity of construction the proximal and distal ends of the cannula insert are conveniently formed from the same material, most conveniently in a single piece. In one preferred configuration the cannula insert comprises a generally cylindrical tube of mouldable elastomer and a divergent portion (flared skirt) both having a uniform wall thickness but the thickness of the divergent portion being less than the thickness of the cylindrical tube. The lesser wall thickness of the divergent portion ensures a high degree of flexibility for the skirt and thereby assists in achieving a good seal with the internal surfaces of the nasal cavity. Optionally the hem can be provided with a peripheral rim of increased thickness so as to strengthen the hem while retaining its flexibility. The rim, which is preferably of the same material as the skirt and formed in one piece therewith, also serves to ensure a good seal within the nasal cavity.

The complete cannula assembly also includes a gas supply portion, usually a plastic tube. The proximal end of the cannula insert can be connected to the said tube by any convenient means, for example by an external or internal fitting to a spigot on the said portion, or can be formed integrally with the supply portion.

The flexible and resilient constructional material should be selected from medically-compatible rubbers and other elastomers. Silicone rubber is generally preferred.

In one advantageous embodiment of the invention the proximal portion of the above-defined cannula insert element is provided with one or more orifices. The orifice-version offers the advantage of a loose fitting insert in avoiding prolonged inhalation of high concentrations of oxygen, in

that even if pure or substantially pure oxygen is fed to the cannula a diluent stream of ambient air enters the cannula through the orifice(s), while retaining the advantage of the insert as defined above in providing a firm fit within the nostril.

The orifice-version cannula insert is thus especially suitable for patients requiring long-term inhalation of oxygen-enriched breathing gas but whose health would be adversely affected by high oxygen concentrations.

The orifice shape is not critical and can for example be circular, oval, square, rectangular or polygonal. In general a circular shape is preferred in that it is easily fabricated and does not provide corners in which dirt could collect.

For most purposes it is preferred to provide a single orifice. This again makes for easy fabrication and facilitates cleaning of the diluent entry channel. Multiple orifices can be provided if desired and indeed the proximal portion can be fabricated wholly or partially from a porous or microporous material.

The total size of the orifice(s) is dictated by the relative volumes of ambient air and oxygen-enriched feed intended to reach the patient. The preferred total size is generally equivalent to a single circular orifice having a diameter in the range 1.2 to 2.5 mm. To some extent the preferred size is dictated by the inhalation pressure which the patient can exert: a weak and infirm patient may require an orifice size at the upper end of the range in order to ensure that sufficient ambient air is inspired.

The orifice(s) can be formed in the insert by a variety of means, for example by punching, drilling or moulding.

The orifice(s) should preferably not be located immediately adjacent to the upstream end (in the direction of flow of oxygen-enriched feed gas) of the proximal portion of the insert. Such a location could mean that the orifice(s) could be partially or wholly blocked by an overlapping portion of the supply tube for the oxygen enriched gas.

Because some of the breathing oxygen is provided by the diluent air the orifice-version offers the advantage of permitting a reduction in the volume of oxygen-containing feed gas. This not only reduces the volume which the feed gas source has to provide but also, if the internal diameter of the supply tube remains unchanged, permits a lower feed pressure. A low feed pressure is desirable to avoid losses of feed gas mixture through the orifice(s) during the inhalation. Because of the relatively small size of the hole and the relatively low pressure employed for breathing gas supplies, loss of feed gas can be kept to a very low level, even during exhalation.

One compromise between the provision of the orifices in, on the one hand, the insert and, on the other hand, the oxygen supply tube is offered by the use of a connecting collar to join the insert to the supply tube and incorporating the orifice(s) in the collar. Another such compromise is offered by incorporating the orifice(s) in a connecting T-piece which divides the oxygen supply tube into two branches, one for each nostril.

It is possible, although generally not necessary, to include means for adjusting the size of the orifice(s) in order to match the particular needs of the patient. If any such matching is required it is usually most conveniently achieved by having a range of inserts with different total orifice sizes. In those instances in which adjustment of a single insert is desirable this can conveniently be provided by a rotatable collar over the orifice portion, the collar itself having an orifice configuration which in one position coincides with the insert orifice configuration, and thereby allows a free air channel into the insert, but in other positions places a solid portion over the insert orifice(s). The collar further provides on rotation between the two positions an infinitely variable range of air channel openings.

Although the orifice version of cannula insert offers less complete control than non-orifice versions over the breathing mixture reaching the patient, a suitable choice of oxygen feed rate and of cannula orifice according to the individual patient's needs can ensure that the breathing mixture is kept close to the ideal proportions. In this regard the orifice insert has the advantage over a loose-fitting insert that the size of air channel is known with precision, whereas the size of open air channel around a loose fitting insert is both unknown and variable.

Thus the orifice-version of cannula described herein also ensures that the breathing mixture reaching the patient has substantially the ideally selected proportions and that the said proportions are maintained throughout the period of administration or until adjusted as required under medical supervision.

It will be appreciated that a similar effect to that of the orifice-version of cannula can be provided by employing a cannula with no orifice and instead providing one or more orifices in the downstream end of the oxygen supply tube. This alternative arrangement is however not preferred since it requires the use of special, non-standard, oxygen tubes which in merely having small orifices at one end would not be easily distinguished from the standard oxygen tubes and could inadvertently be inserted into a gas supply arrangement in which the loss of gas through the orifices could create hazards or other problems.

For most duties it is desirable to provide the patient with two cannulas, one for each nasal cavity. Although the oxygen will generally be delivered from storage or from a generator by a single supply line the line preferably divides into two branches, one for each cannula. A convenient configuration is provided by a supply line which leads from the oxygen source to the rear of the patient's head where the line divides into two branches which pass over respectively the left and right ears to the left and right nostrils.

In a further embodiment of the invention a supply line feeding two cannulas is provided with adjustment means to permit the lateral distance between two cannulas to be varied so as to fit different users. In practice it is found that a single set distance between two cannulas does not comfortably accommodate all patients. The adjustment means is conveniently provided by having a separate supply line branch to each of the cannulas and a variable bridge portion between the separate branches. The bridge is conveniently a sliding tubular member fitting inside the respective branches and providing a bridge between them.

The bridge portion is preferably formed of a rigid, medically compatible, plastic material.

Measured when the cannula is outside the nasal cavity the angle of divergence of the surface of the skirt portion from an axial line through the internal channel of the cannula is preferably in the range 25 to 45°. Within this range the resilience of the constructional material ensures a firm but comfortable fit of the skirt hem to the internal nasal surfaces.

Combined with a good fit of the cannula inserts in the respective cavities this ensures that no significant volumes of ambient air are inhaled with the administered gas mixture.

The good fit of the cannula inserts also ensures that they are held firmly in the nasal cavity. Use of branched oxygen supply lines passing over the ears also assists in holding them in position. Additional securing means can be provided if desired, for example by securing the gas supply line to the upper lip, but are generally not necessary. Thus a firm hold can even be maintained with the foldback type of cannula during exhaling since the exhaled gas does not lift the hem away from the internal nasal surfaces at all points around the hem periphery.

The supply line or lines can optionally include a bellows unit or other reservoir for administered gas so as to ensure that the patient can if required draw in the gas at a fast rate, for example when undertaking deep breathing.

The relative proportions of gases in the administered mixture are selected as required for the desired duty. The cannula according to the invention ensures that the selected

mixture is delivered to the patient in substantially the selected proportions and that the said proportions are maintained throughout the period of administration or until adjusted as required under medical supervision.

The invention is further described below with reference to the accompanying drawings, in which:

Figure 1 is a view of a cannula insert according to the invention;

Figure 2 is a further view of the cannula insert of Figure 1 in the "folded-back" configuration;

Figure 3 is a sectional view of the cannula insert taken along the line A-A in Figure 1;

Figure 4 is a sectional view of the cannula insert taken along the line B-B in Figure 2;

Figure 4a is a sectional view of a modified version of cannula insert taken from a similar position as figure 4; and

Figure 5 is a diagrammatic representation of the Figure 1-4 cannula in place in a nasal cavity.

Figure 6 is a view of a cannula insert similar to that illustrated in Figure 2 but additionally incorporating an orifice in the stem.

Figure 7 is a sectional view of the cannula insert of Figure 6, taken along the line C-C in Figure 6.

Figure 8 is a sectional view, not to scale, of two cannula inserts of the type shown in Figures 1 to 4 and joined together by a variable bridge portion in their oxygen supply line.

The illustrated cannula inserts comprise a tubular proximal portion 2 and a divergent distal portion 4 formed of a single piece of silicone rubber and together defining a flow passage 6 for the administration of breathing gases. The wall thickness of the divergent portion 4 is less than that of the tubular portion 2, rendering the periphery (hem) 8 extremely flexible. Prior to insertion in a nasal cavity 12 the portion 4 is folded back to create a flexible skirt 4' around the tubular portion 2, i.e. the configuration shown in Figures 2, 4 and 5. Two inserts of the folded back configuration are then connected via their tubular portions 2 to a gas supply tube 10 and are each inserted into a nasal cavity 12.

The version of cannula insert illustrated in Figure 4a additionally includes a thickened peripheral rim 9 around the hem 8. The rim 9 is also formed in the same piece of silicone rubber as the rest of the cannula insert.

The dimensions of the illustrated cannula inserts are: external diameter of the divergent portion 5.5 mm; wall thickness of the divergent portion 0.6 mm; wall thickness of the skirt hem 0.4 mm; external diameter of the skirt hem 15.0 mm (15.5 mm in the Figure 4a version); and skirt length 12.0 mm. The angle of divergence of the skirt 4' relative to the axis of the channel 6 is 30°.

The gas mixture is selected according to the available supply source and the specific needs of the individual patient. During inhalation the slightly reduced pressure within the nasal cavity 12 compared with the ambient atmospheric pressure ensures that the hem 8 (or rim 9) is pressed against the internal surface 14 of the cavity 12 such that substantially no gases other than those being administered are inhaled by the patient. During exhalation the slightly raised pressure of the exhaled gases and the configuration of the skirt 4' cause part of the hem 8 (or rim 9) to move away from the surface 14 and permit the exhaled gases to escape through the gap thus formed.

The cannula insert of Figures 6 and 7 again comprises a tubular proximal portion 2 and a divergent distal portion 4 formed of a single piece of silicone rubber and together defining a flow passage 6 for the administration of breathing gases. The distal portion 4 has a hem 8 and for use in a nasal cavity is folded back to create a flexible skirt 4' around the tubular portion 2. The insert additionally comprises a single orifice 7 in the wall of the tube 2.

In use the outer end (lower end as viewed) of the tube 2 is connected to a feed tube (not shown) for the supply of a breathing gas mixture. The gas mixture is selected according to the available supply source and the specific needs of the individual patient. During inhalation the supplied gas mixture is diluted by ambient air drawn into the flow passage through the orifice 7. The reduced pressure within the nasal cavity compared with the ambient atmospheric pressure ensures that the hem 8 is pressed against the internal surface of the cavity and holds the insert in place. During exhalation the slightly raised

pressure of the exhaled gases and the configuration of the skirt 4' cause part of the hem 8 to move away from the inner nasal surface and permit the exhaled gases to escape through the gap thus formed rather than through the orifice 7.

In the configuration shown in Figure 8 two cannula inserts of the type shown in Figures 1 to 4 are connected to branches 10a and 10b of an oxygen supply line. The branches 10a and 10b extend beyond the point at which they are connected to the respective cannulas into portions 20a and 20b with end closure walls 21a and 21b, the said walls having circular central openings 22a and 22b respectively. A variable bridge portion, indicated generally by the numeral 25, comprises a central tube 26 and two end flanges 27 and 28. The tube 26 passes through the openings 22a and 22b into the extended portions 20a and 20b of the oxygen supply tube. The end flanges 27 and 28 are thus located within the extended portions 20a and 20b and form a firm but slidable fit therein.

Adjustment of the lateral distance between the two cannula inserts is achieved by moving one or both of the tube extensions 20a and 20b relative to the bridge portion 25. The selected lateral distance does not affect the supply of oxygen to the respective cannula inserts since oxygen can continue to flow through the branches 10a and 10b to the inserts and through the central tube 26. The close fit of the bridge portion 25 within the tube ends 20a and 20b ensures no significant losses of oxygen from the provision of the adjusting arrangement.

CLAIMS

1. A nasal cannula comprising a generally tubular insert element which has a distal portion (4) to be placed in a nasal cavity and a proximal portion (2) for connection to a supply line (10) for oxygen or oxygen-enriched gas, characterised in that the distal portion (4) is formed of a flexible and resilient material and has a divergent, generally frusto-conical, configuration.

2. A nasal cannula as claimed in claim 1, in which the divergent portion is folded back such that it forms a flared skirt (4') extending around the proximal portion (2).

3. A nasal cannula as claimed in claim 1 or claim 2, in which the proximal and distal portions (2 and 4) of the cannula are formed from a single piece of the same material.

4. A nasal cannula as claimed in claim 3, in which the insert element comprises a generally cylindrical tube (2) of mouldable elastomer and a divergent portion (4) both having a uniform wall thickness but the uniform wall thickness of the divergent portion is less than the uniform wall thickness of the cylindrical tube.

5. A nasal cannula as claimed in any preceding claim, in which the end of the distal portion (4) having the widest diameter is provided with a peripheral rim (9) of increased strength.

6. A nasal cannula as claimed in any preceding claim, in which one or more orifices are provided in one or more of: the supply line (10); the proximal portion (2) of the insert element; a connecting collar to join the insert to the supply line (10); and a connecting T-piece which divides the oxygen supply tube into a branch for each nostril.

7. A nasal cannula as claimed in claim 6, in which the total cross-sectional area of the orifice(s) is equivalent to that of a single circular orifice having a diameter in the range 1.2 to 2.5 mm.

8. A nasal cannula as claimed in claim 6 or claim 7, which includes means for adjusting the size of the orifice(s).

9. A nasal cannula as claimed in claim 8, in which the adjustment is provided by a rotatable collar over the orifice portion, the collar having an orifice configuration which in one position coincides with the insert orifice configuration and in other positions places a solid portion over the insert orifice(s).

10. A nasal cannula as claimed in any preceding claim, in which the supply line (10) feeds two cannulas and is provided with adjustment means to permit the lateral distance between their insert elements to be varied.

11. A nasal cannula as claimed in claim 10, in which the adjustment means is provided by a variable bridge portion between separate branches (10a, 10b) of the supply line.

12. A nasal cannula as claimed in any preceding claim, in which (measured when the cannula insert element is outside the nasal cavity) the angle of divergence of the surface of the distal portion (4) of the cannula from the proximal portion (2) is in the range 25 to 45°.

AMENDED CLAIMS

[received by the International Bureau on 22 October 1992 (22.10.92);
original claims 1 and 3 amended; claim 2 cancelled;
remaining claims unchanged (1 page)]

1. A nasal cannula comprising a generally tubular insert element which has a distal portion (4) to be placed in a nasal cavity and a proximal portion (2) for connection to a supply line (10) for oxygen or oxygen-enriched gas, characterised in that the distal portion (4) is formed of a flexible and resilient material and has a divergent, generally frusto-conical, configuration and in that the divergent portion is folded back such that it forms a flared skirt (4') extending around the proximal portion (2).

3. A nasal cannula as claimed in claim 1, in which the proximal and distal portions (2 and 4) of the cannula are formed from a single piece of the same material.

4. A nasal cannula as claimed in claim 3, in which the insert element comprises a generally cylindrical tube (2) of mouldable elastomer and a divergent portion (4) both having a uniform wall thickness but the uniform wall thickness of the divergent portion is less than the uniform wall thickness of the cylindrical tube.

5. A nasal cannula as claimed in any preceding claim, in which the end of the distal portion (4) having the widest diameter is provided with a peripheral rim (9) of increased strength.

STATEMENT UNDER ARTICLE 19

The claims of the application have been amended to more clearly distinguish the invention from the cited prior art.

Claim 1 now specifies that the divergent portion of the cannula has a folded-back construction which forms a flared skirt extending around the proximal portion. This construction of the cannula leads to certain advantages. These advantages include ease of manufacture, the provision of a rounded distal end to the cannula and a resiliency which results in a surprisingly good seal between the skirt and the nasal cavity. This sealing effect is important to ensure that gas supplied to the cannula is not wasted by leakage.

Furthermore, the simplified structure of the cannula according to the invention, compared to the devices described in the cited prior art, enable a light-weight, unobtrusive device to be produced which provides comfort in use and the greater possibility of long-term use.

As a consequence of the amendment to Claim 1, a corresponding amendment to the description will, in due course, be necessary. On page 3 as filed, the paragraph beginning at line 3 will need to be brought into line with the wording of the amended Claim 1. Furthermore, on page 4, the opening words of the final paragraph will need to be amended to delete the words "preferred version of".

As a consequence of the amendment to Claim 1, no amendment to the drawings is anticipated.

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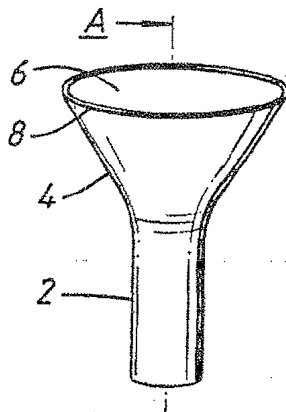


Fig. 1.

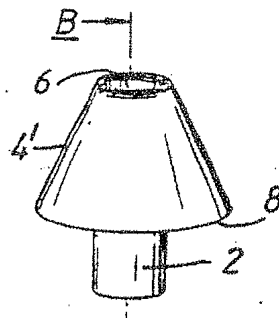


Fig. 2.

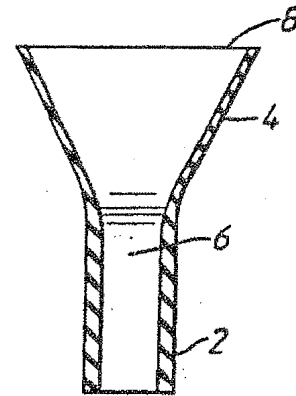


Fig. 3.

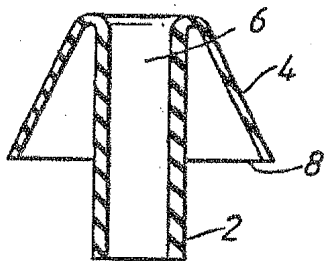


Fig. 4.

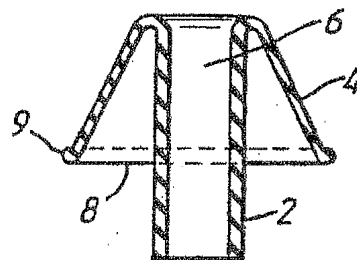


Fig. 4a.

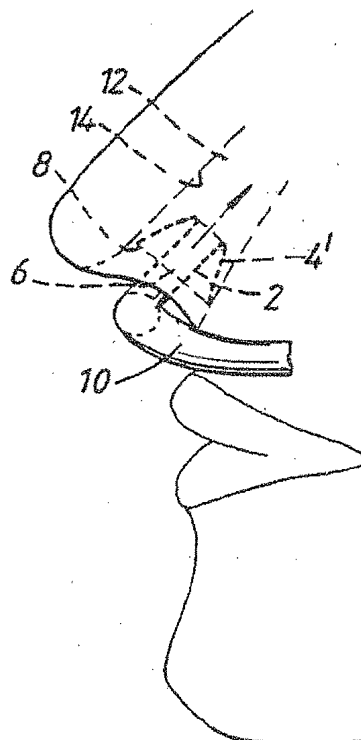


Fig. 5.

SUBSTITUTE SHEET

2/2

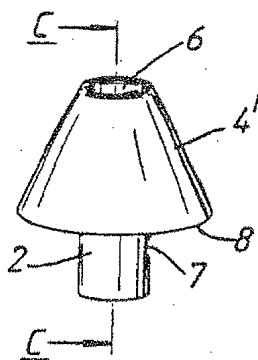


Fig. 6.

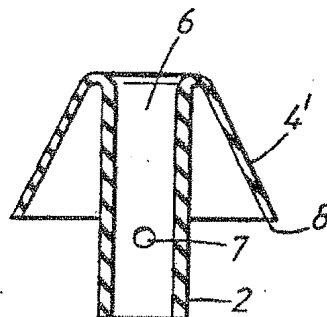


Fig. 7.

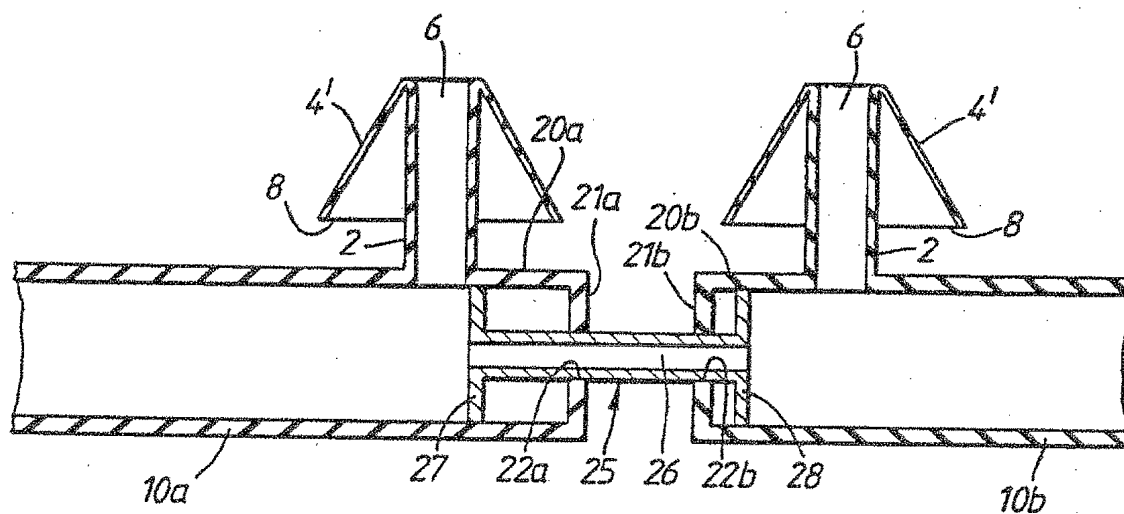


Fig. 8.

SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 92/00940

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all)⁶

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M16/00

II. FIELDS SEARCHED

Minimum Documentation Searched⁷

Classification System

Classification Symbols

Int.Cl. 5

A61M

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched⁸III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹

Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	US,A,4 660 555 (PAYTON) 28 April 1987	1,3,6,7, 12
Y	see column 4, line 15 - line 40; figures 1-6 ----	8-11
X	FR,A,2 638 361 (DIFFUSION TECHNIQUE FRANCAISE) 4 May 1990 ----	1-3,12
Y	DE,A,455 191 (HASSENKAMP) 15 June 1926 see page 2, line 8 - line 59; figures ----	8-9
Y	US,A,4 422 456 (TIEP) 27 December 1983 see abstract; figures 2,4,5 ----	10,11
A	US,A,4 782 832 (TRIMBLE ET AL.) 8 November 1988 ----	-

¹⁰ Special categories of cited documents:

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IV. CERTIFICATION

Date of the Actual Completion of the International Search

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ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.

GB 9200940
SA 59590

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4660555	28-04-87	None	
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82